

## **Summary of the Environmental Laboratory Advisory Board (ELAB) Meeting January 16, 1998**

The Environmental Laboratory Advisory Board (ELAB) met on Friday, January 16, 1998, at 1:00 p.m. Eastern Standard Time (EST) in conjunction with the Third NELAC Interim Meeting in Arlington, VA. The meeting was led by co-chairs Dr. Wilson Hershey and Ms. Ramona Trovato. A list of action items is given in Attachment A. A list of participants is given in Attachment B. An inclusive list of ELAB recommendations is given in Attachment C.

### **INTRODUCTION**

The meeting was opened by Dr. Hershey by introducing members of the ELAB. The operation and purpose of the ELAB as a federal advisory committee was reviewed by the Designated Federal Officer Jeanne Mourrain and Ms. Trovato.

### **IMPLEMENTATION OF NELAC**

A report on the implementation of NELAC was given by Ms. Carol Batterton, NELAC Chair, noting that a very successful third interim meeting of NELAC has just been concluded with more than 250 participants. A summary of a survey of the States regarding their plans for implementing NELAC was distributed. Seventeen States have indicated they will apply for NELAC accreditation by January 1998 and an additional 10 States indicated they will apply before October 1998. Three applications for NELAC certification have been received to date. As part of the interim meeting the NELAC Board of Directors met with EPA acting Assistant Administrator (AA) for the Office of Research and Development (ORD) and with the AA for the Office of Solid Waste (OSW) to discuss Agency concerns for the implementation of NELAC. EPA concerns regarding the NELAC Quality Systems Chapter were allayed after the discussion with the Board.

### **NELAC RESPONSE TO ELAB RECOMMENDATIONS**

The status of ELAB recommendations to NELAC resulting from the July 28, 1997 Dallas meeting were reviewed.

**Recommendation 1:** ELAB recommends that EPA prepare a working set of PT sample design criteria which meet Program Office requirements to be used by the Proficiency Testing Oversight Body (PTOB) to include, at a minimum, concentration, interferences, media.

*Discussion:* NELAC is working with EPA/EMMC to develop specifications for proficiency testing (PT) sample design criteria for use by the Proficiency Testing Oversight Body (PTOB). EPA is also working with NIST to develop a draft of the standard. The draft is currently awaiting response from EPA.

*Action:* Recommendation remains open. ELAB wishes to reinforce that the recommendation is still important.

**Recommendation 2:** ELAB recommends that NELAC/NIST/EPA develop a protocol which can be used by the PTOB, through review and analysis of data, to assure program equivalence among

PT providers. (See attached paper by Dan Tholen for starting point.) ELAB further recommends that this protocol be finalized as soon as possible to ensure the integrity of this program.

Discussion: The NELAC PT committee has worked with NIST and EPA to produce a draft standard for PTOB to assure equivalence among PT providers. An overview of the draft document, Handbook 150-xx, was given by NIST in the NIST Open Meeting on the morning of January 16, 1998. NIST reviewed Handbook 150-xx and requested public comments by March 15, 1998. Members of the ELAB were impressed with the draft document and the cooperation with NIST and EPA.

Action: ELAB will send a letter to EPA and NIST complimenting them on their work to date on developing Handbook 150-XX.

**Recommendation 3:** ELAB recommends that the periodic PT studies occur at fixed times throughout the year. ELAB further recommends that initial and remedial PT samples may be obtained outside this schedule.

Discussion: ELAB has formerly recommended to NELAC that periodic PT studies be conducted at fixed times throughout the year. The problems created by labs not being able to receive or reinstate accreditation due to scheduling were discussed.

Action: ELAB is concerned about the effect of having only two opportunities per year for obtaining PT samples, will have on the accreditation process, both initial and remedial. ELAB recommends that NELAC ensure that the PT system not delay the laboratory accreditation process by more than thirty days.

**Recommendation 4A:** ELAB recommends that the long range goal of NELAC be to develop a consistent approach to both scope of accreditation and PT program sample design, which recognizes the needs of the laboratories, the primary accrediting authorities, and the Agency, particularly with regard to performance based methods, similar technologies, and analytical capabilities.

Discussion: The goal to develop a consistent scope of accreditation and PT programs has been endorsed by the NELAC PT Committee. ELAB discussed the need for the scope of accreditation and PT programs to address performance based measurement systems (PBMS), similar technologies, and analytical capabilities. It was suggested since PBMS is still under development by EPA, NELAC should monitor progress in this program but avoid any delays in the implementation of the NELAC PT program.

Action: Recommendation remains open.

**Recommendation 4B:** ELAB recommends that the PTOB, during implementation of the PT program, require that each PT provider record and report PT results to both the accrediting authority and the PTOB on a method basis, by matrix and analyte.

Discussion: NELAC is awaiting EPA specifications for reporting by method, matrix, and analyte. ELAB will recommend that the Proficiency Testing Oversight Body (PTOB) require that each PT provider record and report PT results to both the accrediting authority and to the PTOB to meet the EPA specifications.

Action: Recommendation remains open.

**Recommendation 4C:** ELAB recommends that a task group monitor the impact on implementation of the discrepancy between PT program design and the scope of accreditation.

Discussion: None

Action: Recommendation remains open.

**Recommendation 5:** ELAB recommends that there is consistency between NELAC Standards and the EPA's PT Externalization program.

Discussion: NELAC is working closely with EPA and EMMC to insure that NELAC standards are consistent with EPA's PT externalization program. A PT Committee meeting with EMMC in September indicates close cooperation in developing consistent PT standards.

Action: Recommendation remains open.

**Recommendation 6:** ELAB recommends that the proposed PT standards (including the Appendices) be adopted as presented.

Discussion: The recommendation to adopt the proposed PT standards has been accomplished.

Action: Completed

**Recommendation 7:** ELAB recommends that the GLP decisions and the NELAP timeline be decoupled.

ELAB further recommends that the GLP subcommittee report to the ELAB at the Interim Meeting with three options including a) status quo; b) Options 1 + 3 + 5; and c) lab accreditation.

ELAB further recommends that ISO Guide 25 be explicitly considered to understand the value it offers to the GLP process.

ELAB further recommends that the NELAC process be evaluated to identify the value added, if any. EPA will provide language to clarify that the NELAC Constitution and Bylaws reflect that decision-making and implementation of the GLP Program will continue as an exclusively federal program.

The goal of this activity is to provide information to OECA and OPPTS management for a decision regarding the direction of the GLP program.

Discussion: Addressed in the GLP report (see below).

Action: Teleconference to be scheduled to make final decision on recommendation to EPA.

**Recommendation 8:** ELAB recommends that before EPA promulgates a regulation, it must demonstrate and document that MQOs are achievable using available measurement technology.

Discussion: This recommendation was reconsidered and determined to need modification.

Action: ELAB recommends that before EPA publishes a method, whether in regulation or guidance, the method must be demonstrated reliable for its stated use.

**Recommendation 9:** ELAB recommends that EPA demonstrate that any new or revised regulatory measurement requirements are achievable on samples that represent the same level of analytical challenge as the matrix for which the regulation is intended. (Ideally, this would be samples of the actual matrix to be monitored, as defined by the regulation.)

Discussion: The Board voted to include an additional clarifying phrase to the recommendation.

Action: Add the parenthetical phrase: (That is, don't publish a regulation without a method that works.)

**Recommendation 10:** ELAB recommends that EPA consider the following remaining important unresolved issues:

- PB Measurement System vs. PB Method
- Sample matrix
- Method Validation
- Method Compliance
- Interlaboratory Comparability
- Cost
- Laboratory Client Relationship

Discussion: None

Action: Recommendation remains open.

**Recommendation 11:** ELAB recommends that the initial approval of accrediting authorities should occur simultaneously.

Discussion: The NELAC Transition Committee has implemented this recommendation.

Action: Completed.

**Recommendation 12:** ELAB recommends that the first round of NELAC accreditation of laboratories by accrediting authorities should also occur simultaneously.

Discussion: The NELAC Transition Committee has implemented this recommendation.

Action: Recommendation closed.

**Recommendation 13:** ELAB recommends that prior to the designation of approved proficiency test (PT) sample providers as required by Chapter 2, accredited labs should be allowed to continue using existing PT sample providers. However, in the interim, frequency of PT sample analysis as required by Chapter 2 must be met.

Discussion: The NELAC Transition Committee has implemented this recommendation.

Action: Completed.

**Recommendation 14:** ELAB recommends that Chapter 6 be further defined regarding Accrediting Authority recognition of States to address the conflict of interest between public and private sector labs, with respect to a State laboratory conducting routine environmental testing analyses. Further definition will include the specific guidance to avoid conflict of interest for an above stated Accrediting Authority.

Discussion: The NELAC Accrediting Authority Committee has implemented this recommendation.

Action: Completed.

**Recommendation 15:** ELAB recommends that the issue of primacy State laboratories in accrediting non-primacy State laboratories be referred to the Accrediting Authority Committee for further consideration.

Discussion: The NELAC Accrediting Authority Committee has implemented this recommendation.

Action: Completed.

**Recommendation 16:** ELAB strongly recommends a vote for adoption of the Standards with modifications as specified and passed by ELAB motions on July 28, 1997.

Discussion: NELAC adopted the standards.

Action: Completed.

**Recommendation 17:** ELAB recommends that EPA Program Offices become more active in NELAC and promulgate regulations that are consistent with the NELAC standards as appropriate.

Discussion: Nancy Wentworth, co-chair of the EMMC Panel on Laboratory Accreditation, discussed the steps that are being taken within the Agency to obtain a consensus opinion.

Action: Recommendation remains open. In addition, ELAB will send a letter to EPA's Assistant Administrator for the Office of Research and Development, noting that NELAC is awaiting critical input from EPA Program Offices through EMMC. ELAB encourages the Agency to provide that input in writing as soon as possible.

## **EMMC RESPONSE TO ELAB RECOMMENDATIONS**

Nancy Wentworth noted that the Agency has policies for monitoring quality assurance and requires program peer review. EPA has QA managers across the Agency who can serve as committee members or at least as a resource for NELAC committees. The Agency is in the process of working to implement performance based measurement systems (PBMS) and NELAC should adopt these procedures when they are available. The Quality System Committee has addressed the concern for compatibility with PBMS and is awaiting input from EMMC. EPA EMMC representatives suggested that Agency QA managers should work with NELAC committees to insure NELAC and EPA interests are consistent. It was also noted that EPA has many programs and people with interests in NELAC and that EPA acknowledges that they should do a better job of speaking with one voice on these issues.

Concern was expressed that Recommendations 8 and 9 should contain language to prevent the use of methods that are not capable of meeting the monitoring quality objective. The ELAB agreed that a recommendation should be made to EPA that it publish regulations only when there is an analytical method which has been demonstrated capable of supporting the objective of the monitoring.

## **PREVIOUS RECOMMENDATIONS**

Members asked that Recommendations from the ELAB meeting of February 6, 1997, be included in all future status discussions. Those recommendations (provided after the meeting) were as follows:

1. The GLP Subcommittee will present a final report and recommendations at the next ELAB meeting in July.  
Status: Completed
2. ELAB members will make the following recommendations to EMMC and the NELAC Board of Directors regarding proficiency testing:
  - a. The issue of how to define the basis for NELAC accreditation is of concern to the laboratory community and should continue to be addressed jointly by the NELAC Committees on Proficiency Testing and Program Policy and Structure. ELAB participation in the effort

will be the responsibility of Mr. Coyner and Ms. Moore, who are members of the Proficiency Testing and Program Policy and Structure Committees, respectively.

Status: Ongoing.

- b. That the goal of the NELAC PT program should be to provide full-volume, real-world samples, keeping in mind considerations of practicality and cost.

Status: Ongoing.

- c. That USEPA serve as the oversight body for the PT program, with the necessary resources and commitment to improve the current system. Alternatively, ELAB recommends that the oversight body be another government organization and that steps be taken to ensure a smooth transition.

Status: Completed - NIST to serve as PTOB.

- 3. ELAB will recommend to the NELAC Board of Directors that the Program Policy and Structure Committee address the issue of how to recognize an appropriate role for Native American Tribal Nations in NELAC.

Status: Ongoing

- 4. With regard to the role of private-sector accrediting bodies in NELAC, ELAB will recommend to the NELAC Board of Directors that the NELAC national database include publicly available information describing the functions performed by individual private organizations for specific State programs.

Status: Ongoing

- 5. With regard to PBMS, ELAB will recommend to the EMMC and the NELAC Board of Directors that:

- a. USEPA's programs and Regions and the States work to implement PBMS consistently.

Status: Ongoing

- b. That training in implementation of PBMS is needed for State laboratory inspectors.

Status: Ongoing

- c. That a representative from the EMMC Work Group on PBMS work with the ELAB PBMS Subcommittee in the future.

Status: Completed

It was requested that a running record be kept of all recommendations. DFO Mourrain will collate all recommendations and renumber them in chronological order.

## COMMENTS ON NELAC STANDARDS

An open discussion period identified “due process” as an issue of concern. The rights of the laboratories to due process in matters concerning revocation of accreditation should be protected by the NELAC process. Specifically, the laboratories should have the right to see any reports concerning its accreditation status before they are released to the general public, there should have a right to appeal any pending action, and there should be a right to confidentiality until an action is final. ELAB members expressed the concern that NELAC should promote a climate to encourage laboratories to correct their errors and avoid punishing labs for discovering and reporting errors. Some representatives reported that the States have the responsibility for protecting public health and assuring the quality of data. The laboratories are forewarned of their responsibility and rarely challenge actions against their accreditation. Others noted that in some cases laboratories have been fined for reporting and correcting erroneous data and that punishment for this may lead to laboratories hiding faulty data.

Action: ELAB recommends that an advisory appendix be written that addresses the issue of due process for laboratories. This appendix must address the rights, responsibilities, and obligations of the laboratories and accrediting authorities. The discussion should include, but not be limited to:

- S the right of the laboratory to see the audit report prior to action;
- S the right of the laboratory to privacy during review;
- S the right of the laboratory to appeal prior to suspension or revocation; and
- S the right of the laboratory to confidentiality.

A second issue identified in the open discussion period was “sampling and field measurements.” It was noted that an ad hoc committee is considering sampling issues. There is a concern that laboratories have no control over the samples submitted to them for analysis and an acknowledgment that sampling is an integral part of any measurement.

Action: ELAB strongly recommends that, during consideration of inclusion of sampling into NELAC standards, all stakeholders be represented.

## **GLP FINAL REPORT**

The Good Laboratory Practices (GLP) Subcommittee distributed a report to ELAB participants addressing an attempt to identify solutions to the perceived inadequacies of the EPA GLP program. The Subcommittee proposed the five ELAB recommendations (ELAB Recommendation 7) concerning GLP be condensed to three. The three options considered by the subcommittee are (1) use existing programs and procedures to upgrade the current process, (2) augment the current program with additional resources, and (3) institute a third party laboratory accreditation program. The subcommittee noted that the NELAC program and the GLP program are very different. The subcommittee members are unanimous in their opposition to including the FIFRA/TSCA GLP in the NELAP. It is also noted that the FDA will not adopt an accreditation program but will continue the GLP program. The GLP program is also recognized internationally due to OECD adoption of the GLP program as their standard. The GLP Subcommittee feels that the rule-making process has not been followed in developing the NELAC standards. The final recommendations of the GLP Subcommittee are (1) total disengagement of the GLP issue and FIFRA/TSCA programs from NELAP, (2) focus on use of existing programs and procedures to upgrade the current process, (3) utilize the rule-making process to amend the US FIFRA/TSCA GLP standards to meet EPA needs and newly revised OECD Principles, and (4) utilize the rule-making process to include the entire GLP regulated community to review and comment on possible solutions. The GLP Subcommittee

further recommended that it be disbanded following this meeting since the GLP issues have been discussed exhaustively and the members have no interest in continuing the activity. The ELAB agreed with the recommendation to disband the Subcommittee and thanked them for its report and its excellent work.

Action: ELAB will meet by teleconference to study the GLP report, decide on the appropriate recommendation(s), and forward the recommendation(s) to the EMMC Policy Council.

## **CONSIDERATION FOR THIRD PARTY ASSESSORS**

A recommendation was made to reinstate the Subcommittee on Third Party Assessors. The subcommittee would provide a report to ELAB on defining the criteria for third party assessors. Several ELAB members felt that the subcommittee could be invaluable to NELAC particularly for dealing with international issues. Others cautioned that there should be care in chartering such a committee because NELAC has defined procedures for determining the competency of assessors. Emphasis was given to having third parties serve as “agents” for the states and not as “authorities.” Ms. Sandra Wroblewski and Dr. William Kavanagh were appointed by the ELAB to serve as co-chairs of the Third Party Assessors Subcommittee. They are requested to draft a charter and functional statement for the subcommittee, recommend potential members, and a list of deliverables. Ms. Wroblewski and Dr. Kavanagh will present the charter, etc. during the above mentioned teleconference.

## **OTHER BUSINESS**

The issue of involving federal agencies other than EPA in the NELAC was discussed. Since other federal agencies are involved as members in various NELAC committees it is believed that the interested agencies are already involved.

Action: ELAB recommends that NELAC invite the Federal Partners Committee to make a report at NELAC IV (June 28, 1998) on their intention to 1) participate in NELAC; b) continue their own programs; and c) to serve as accrediting authorities.

Compatibility of NELAC Quality Systems and PBMS was discussed. ELAB members believe that the two systems are basically compatible but would like to have EPA provide in writing an opinion as to the issue. The Quality Systems Committee has stated that it would like to see increased flexibility in its standard to insure compatibility with other programs. The Quality Systems Committee is planning a face to face meeting with EMMC in Denver in March and will discuss the issue then. The issue will be reported at the next plenary.

Action: ELAB asked Nancy Wentworth to report on the Agency’s action regarding PBMS and how it relates to the Quality Systems Chapter.

EPA requested recommendations for a replacement for Linda Christensen of IAETL to serve on the ELAB.

The meeting was adjourned by DFO Mourrain.

**ACTION ITEMS**  
**Environmental Laboratory Advisory Board (ELAB) Meeting**  
**January 16, 1998**

<b>Item No.</b>	<b>Action Item</b>	<b>Date Completed</b>
1.	ELAB will maintain a list of all recommendation, track the status of all action items, and transmit new and modified recommendations to NELAC/EPA.	
2.	ELAB will send a letter to EPA encouraging a written consensus position on NELAC standards.	
3.	ELAB will send EPA and NIST a written commendation of the NIST/EPA effort in developing Handbook 150-xx.	
4.	ELAB will meet by teleconference to discuss the GLP subcommittee report.	
5.	Sandra Wroblewski and William Kavanagh, co-chairs of the Third Party Assessors Subcommittee will present a draft charter for approval at the upcoming teleconference.	

**PARTICIPANTS**  
**Environmental Laboratory Advisory Board (ELAB) Meeting**  
**January 16, 1998**

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